SEP - 6 2001

K011821

SUMMARY OF SAFETY AND EFFECTIVENESS

A. SPONSOR IDENTIFICATION:

NewDeal SA
Parc d'Activitiés Garigliano
Rue de la Convention
38 200 VIENNE
FRANCE Tél. : (33) 4 74 78 15 15
Fax : (33) 4 74 78 15 16

B. ESTABLISHMENT REGISTRATION NUMBER: 9615741

C. OFFICIAL CONTACT PERSON

Norman F. Estrin, Ph. D., RAC
President
Estrin Consulting Group, Inc.
9109 Copenhaver Drive
Potomac , MD 20854
Tel. : (301) 519-1098
Fax : (301) 519-1389
estrin@yourFDAconsultant.com

D. DATE OF PREPARATION OF THIS SUMMARY: June 7, 2001

E. PROPRIETARY (TRADE) NAME: **I.CO.S® Screw**

F. COMMON NAME: Bone fixation screw, Cannulated compression screw

G. CLASSIFICATION NAME AND REFERENCE

Smooth or threaded metallic bone fixation fastener (21 CFR, Section 888.3040)

H. PROPOSED REGULATORY CLASS: Class II

I. DEVICE PRODUCT CODE: 87HWC

J. PANEL CODE: 87 OR Orthopedic

K. DESCRIPTION OF DEVICE:

The "new" **I.CO.S® Screw** is a cannulated compression screw with non-theaded shaft, allowing optimal compression. The head of this screw can be driven forward and translated along the body in order to increase the compression controled by the surgeon. It also has a self-tapping screw tip. It comes in diameters from 4.0 mm to 6.5 mm and in length from 26 to 90. It is identical in design to the **I.CO.S® Screw** (K993762)

L. INDICATIONS FOR USE:

The **"new" I.CO.S® Screw** is indicated for fixation of bone fractures or for bone reconstruction. Examples include:

- Fixation of bone fragments, in long bones or small bones fractures.
- Fractures management in the foot or hand
- Arthrodesis in hand, foot or ankle surgery
- Mono or Bi-cortical osteotomies in the foot or hand or in long bones
- Treatment of inferior tibio fibular diastasis

The size of the chosen screw should be adapted to the specific indication.

M. PREDICATE DEVICE:

The "new" **I.CO.S® Screw** is substantially equivalent in design, composition and function to the **I.CO.S® Screw** and to other orthopedics screws manufactured and cleared for market:

Orthopeadic Biosystem Ltd.:	K963420
AAP Implants Inc.:	K990776
Synthes:	K962823

N. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:

The **"new" I.CO.S screw** is technically equivalent to the device currently approved. They have the same intended use, and the design has not changed Both the **I.CO.S® Screw,** the Self-drilling Facet Screw from Orthopaedic Biosystems Ltd, Synthes sterile 3.0mm-4.5mm-7.0/7.3mm Cannulated screws, and the cannulated screw from AAP implants Inc. have the same intended use and all are indicated for fixing fractures or osteotomies. All are available in Titanium alloys. All of them are self-tapping screws, and most of them are cannulated. All of them have a non threaded part, allowing compression between the two bone fragments.

The **I.CO.S® Screw** meets the ASTM standards (ASTM F136) for the material and design for medical application. The bone screws are of the same thread configuration and length as offered by Orthopeadic Biosystem Ltd, AAP Implants Inc, Synthes and many other orthopaedic companies. The minor and major diameters as well as the head size are comparable. cannulated and are topped with a hexagonal socket.

O. SUMMARY OF STUDIES:

Rupture torque of the "new" **I.CO.S® Screw** is the same as for the device currently cleared, since the design has not changed. It was compared with requirements of the French Standard N°NF-S –90414 and found to have a resistance torsion in compliance with the selected standard.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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NewDeal SA
c/o Norman F. Estrin, Ph.D., RAC
President
Estrin Consulting Group, Inc.
9109 Copenhaver Drive
Potomac, Maryland 20854

Re: K011821
Trade/Device Name: I.CO.S. Screws
Regulatory Number: 888.3040
Regulatory Class: II
Product Code: HWC
Dated: June 7, 2001
Received: June 11, 2001

Dear Mr. Estrin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Susan W. L., M.D.

For Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011821

Device Name: **I.CO.S.®** **SCREW**

Indications for Use:

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The size of the chosen screw should be adapted to the specific indication.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011821